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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,976	11/25/2003	Leon Kaufman	021106-001610US	6927

20350 7590 04/19/2007
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EXAMINER

CHENG, JACQUELINE

ART UNIT	PAPER NUMBER
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3768

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/721,976

Applicant(s)

KAUFMAN, LEON

Examiner

Jacqueline Cheng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-16 and 19-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-16 and 19-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/29/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see page 6, filed October 20, 2006, with respect to the objection of claim 13 have been fully considered and are persuasive. The objection of claim 13 has been withdrawn.
2. Applicant's arguments with respect to claims 1, 5-16, and 19-35 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1, 6-8, 15, 16, 20-22, 29** are rejected under 35 U.S.C. 102(b) as being anticipated by Widder (US 5,611,342). Widder teaches a method for enhanced virtual colonoscopy where a low density (a low or negative HU) contrast agent is introduced by ingestion into the gastrointestinal tract. Preferably the HU is less than 0 HU which would be lower than the density of water (col. 2 line 32-42, col. 3 line 6-11). This low density contrast agent, can be a compound that comprises cellulose (which comprises sawdust) (col. 5 line 8), enhances the imaging of the surrounding structures of the gastrointestinal tract walls, reducing the attenuation signal of the patient's stool to an attenuation level below an attenuation level of the surrounding colon tissue

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(col. 2 line 16-20, col. 6 line 4-21). Widder also discloses that another low density contrast agent that can be used is described in PCT WO92/17514 which are microspheres prepared from biocompatible synthetic polymers (which comprises polystyrene) to contain internal cavities filled with gas (col. 2 line 61-67). These low density contrast agents can also contain fatty acids (lipids) in order to increase gastric retention time which allows for a longer imaging time frame (col. 4 line 34-40).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claim 5, 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Widder.

Although Widder does not explicitly disclose that the introduction of these non-laxative materials results in reducing the patient's stool to a density 80-90% of the density of the surrounding colon tissue, it would be obvious to one skilled in the art to try to reduce the density as much as possible to obtain the best image contrast. Widder discloses tweaking his solutions, their concentration, their density so it is capable that Widder's solutions reduces the patient's stool to a density of 80-90%.

7. **Claims 9-14, 23-28, 30-34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Widder in view of Unger (WO 92/17514). Unger discloses using low density microspheres

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as contrast media for imaging the GI tract. These microspheres lower the patient's stool to an attenuation signal between approximately -30HU to -150HU (page 11 line 25-28). Unger also teaches incorporating gasogen agents into the contrast medium to distend the GI tract (page 14 line 3-11) which increases heterogeneity (as disclosed by the applicant, paragraph 0014). How the non-laxative material that stimulates gas is administered would be a design choice, whether it be as air in a membrane, such as Unger already discloses air-filled microspheres which could be an air filled closed cell foam. All these materials, or any materials that would be needed for a virtual colonoscopy can be put together in a kit for convenience (page 14 line 12-25).

8. **Claim 35** is rejected under 35 U.S.C. 103(a) as being unpatentable over Widder in view of Vining (US 6,901,277 B2). Although Widder does not explicitly disclose using thresholding of attenuation levels to isolate the patient's stool from the patient's colon, since the purpose of the low density contrast agent and imaging is to enhance the colon in the image, it would be obvious to one skilled in the art to apply a thresholding process to further the utility of Widder to further enhance the image of the colon. Applying such a thresholding process based upon attenuation levels is well known in the art as disclosed by Vining. Vining discloses using an attenuation range of the organ of interest as the thresholding value, which in the case of Widder would be a value lower than the signal of the colon, but higher than the signal of the stool.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC


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